

SMG 1280.30

FDA STAFF MANUAL GUIDES, VOLUME I - ORGANIZATIONS AND FUNCTIONS

FOOD AND DRUG ADMINISTRATION

OFFICE OF MEDICAL PRODUCTS AND TOBACCO

CENTER FOR DRUG EVALUATION AND RESEARCH

OFFICE OF PHARMACEUTICAL QUALITY

OFFICE OF NEW DRUG PRODUCTS

Effective Date: September 26, 2014

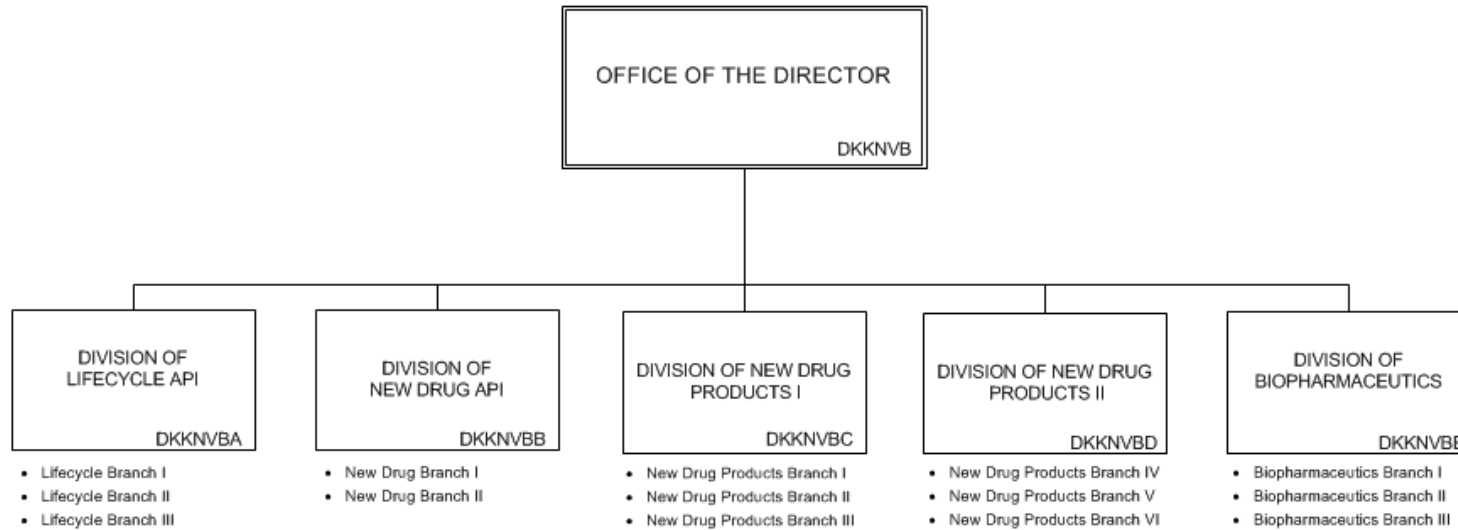
1. OFFICE OF NEW DRUG PRODUCTS (DKKNVB).

- A. Conducts team-based, cross-office collaborative evaluation and assessment of Investigational New Drug (IND) and original New Drug Application (NDA) submissions, and active pharmaceutical ingredient (API) information supporting Abbreviated New Drug Applications (ANDAs).
- B. Conveys risk-informed recommendations on the approvability of such products to appropriate stakeholders Office of New Drugs (OND), other offices within Office of Pharmaceutical Quality (OPQ), industry, and is responsible for the communication of product-specific residual risk identified in the pre-marketing arena.
- C. Serves as a Liaison to OND, will work collaboratively with other offices in OPQ to conduct review of applications, will participate in inspections as needed.

2. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Office were approved by Commissioner of Food and Drug Administration and effective on September 26, 2014.

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The following is the Food and Drug Administration, Office of Medical Products and Tobacco, Center for Drug Evaluation and Research, Office of Pharmaceutical Quality, Office of New Drug Products organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR – DKKNVB:

- DIVISION OF LIFECYCLE API – DKKNVBA
 - Lifecycle Branch I
 - Lifecycle Branch II
 - Lifecycle Branch III
- DIVISION OF NEW DRUG API – DKKNVBB
 - New Drug Branch I
 - New Drug Branch II
- DIVISION OF NEW DRUG PRODUCTS I – DKKNVBC
 - New Drug Products Branch I
 - New Drug Products Branch II
 - New Drug Products Branch III
- DIVISION OF NEW DRUG PRODUCTS II – DKKNVBD
 - New Drug Products Branch IV
 - New Drug Products Branch V
 - New Drug Products Branch VI
- DIVISION OF BIOPHARMACEUTICS – DKKNVBE
 - Biopharmaceutics Branch I
 - Biopharmaceutics Branch II

- Biopharmaceutics Branch III